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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,152	08/04/2006	James Peter Burnie	87278.2760	8989

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EXAMINER	
SWARTZ, RODNEY P	

ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
04/23/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@bakerlaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/553,152	BURNIE ET AL.	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-21 and 23-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *19-21 and 37-39* is/are allowed.

6)☒ Claim(s) *23-36 and 40-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4-7-10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. THE FINALITY OF THE LAST OFFICE ACTION IS HEREBY VACATED.

2. Applicants' Response to Office Action, received 7 April 2010, is acknowledged. Claims 23, 24, 25, 26, 27, 28, 29, 31, 32, 33, 34, 35 and 36 have been amended. Claim 22 has been cancelled. The submitted Terminal Disclaimer has been approved and entered.

3. Claims 19-21 and 23-43 are pending and under consideration.

Rejections Withdrawn

4. The rejection of claims 19, 20 and 21 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2 and 4 of U.S. Patent No. 7,608,265, issued on 27 October 2009, is withdrawn in light of the submitted Terminal Disclaimer.

5. The rejection of claims 22-36 under 35 U.S.C. 112, second paragraph, as being indefinite for antibodies "specific against at least one antigen", is withdrawn in light of the claim amendments.

6. The rejection of claims 37-39 under 35 U.S.C. 112, second paragraph, as being indefinite for dependence from rejected claims, is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 23-36 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 40 is a method for identifying candidate sequences specific against at least one antigen produced by *C. difficile*.

The steps of the method comprise:

(i) obtain B cells from $\geq$1 patient exposed to the antigen;

(ii) sequencing from said B-cells at least CDR3 regions of variable heavy chains or variable light chains, or both;

(iii) detecting a set of sequences that occur in total at a frequency of $\geq$1%, wherein said set includes a dominant sequence and sequences of $\geq$80% homology to said dominant sequence; and

(iv) confirming that antibodies or antigen binding fragments of said antibody comprising the dominant sequence of step (iii) binds specifically to the antigen produced by *C. difficile*.

It is unclear what is being claimed concerning the "sequences of $\geq$80% homology to said dominant sequence", because only the dominant sequence is tested for confirming that it bind specifically to said antigen of *C. difficile*.

Claims 23-36 depend from claim 40, but do not clarify the issue.

8. Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP

§ 2172.01. The omitted steps are: methods of identifying sequences which are effective to clear *C. difficile* infection.

The claim is the method of claim 40.

Claim 40 is a method for identifying candidate sequences specific against at least one antigen produced by *C. difficile*. Claim 40 contains no methods for determining which, if any, of the confirmed sequences can clear infection by *C. difficile*.

The instant claim recites "wherein sequences from the recovered patient are compared with sequences from the patient who has not recovered to identify sequences that are effective to clear the infection". This comparison, at most, would only identify differences in the sequences. The ability of such sequences to clear infection would remain to be discerned by some other steps, which are not contained in the instant claim.

9. Claim 41 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 41 is a method for identifying candidate sequences specific against at least one antigen produced by *C. difficile*.

The steps of the method comprise:

(i) obtain B cells from $\geq$2 patients exposed to the antigen;

(ii) sequencing from said B-cells at least CDR3 regions of variable heavy chains or variable light chains, or both;

(iii) detecting a set of sequences that occur in total at a frequency of $\geq$1%, wherein said set includes a dominant sequence and sequences of $\geq$80% homology to said dominant sequence; and

(iv) confirming that antibodies or antigen binding fragments of said antibody comprising the dominant sequence of step (iii) binds specifically to the antigen produced by *C. difficile*.

It is unclear what is being claimed concerning the "sequences of ≥80% homology to said dominant sequence", because only the dominant sequence is tested for confirming that it bind specifically to said antigen of *C. difficile*.

10. Claim 42 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 42 is a method for identifying candidate sequences specific against at least one antigen produced by *C. difficile*.

The steps of the method comprise:

(i) obtain B cells from ≥1 patient exposed to the antigen;

(ii) sequencing from said B-cells at least CDR3 regions of variable heavy chains or variable light chains, or both;

(iii) comparing the sequences of step (ii) with sequences of CDR3 regions of variable heavy chains or variable light chains, or both, from a patient that has not been exposed to said antigen;

(iv) detecting a set of sequences that occur in total at a frequency of ≥1% in sequences identified in step (ii) and at a frequency of <1% in sequences from the patient that has not been exposed to said antigen, wherein said set includes

a dominant sequence and sequences of ≥80% homology to said dominant sequence; and

(v) confirming that antibodies or antigen binding fragments of said antibody comprising the dominant sequence of step (iii) binds specifically to the antigen produced by *C. difficile*.

It is unclear what is being claimed concerning the "sequences of ≥80% homology to said dominant sequence", because only the dominant sequence is tested for confirming that it bind specifically to said antigen of *C. difficile*.

11. Claim 43 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 43 is a method for identifying candidate sequences specific against at least one antigen produced by *C. difficile*.

The steps of the method comprise:

(i) obtain B cells from ≥1 patient prior to exposure to the antigen;

(ii) sequencing from said pre-exposure B-cells at least CDR3 regions of variable heavy chains or variable light chains, or both;

(iii) obtain B cells from said ≥1 patient after exposure to the antigen;

(iv) sequencing from said post-exposure B-cells at least CDR3 regions of variable heavy chains or variable light chains, or both;

(v) detecting a set of sequences that occur in total at a frequency of $\geq$1% in sequences identified in step (iv) and at an increased frequency of with respect to sequences identified in step (ii), wherein said set includes a dominant sequence and sequences of $\geq$80% homology to said dominant sequence; and

(vi) confirming that antibodies or antigen binding fragments of said antibody comprising the dominant sequence of step (v) binds specifically to the antigen produced by *C. difficile*.

It is unclear what is being claimed concerning the "sequences of $\geq$80% homology to said dominant sequence", because only the dominant sequence is tested for confirming that it bind specifically to said antigen of *C. difficile*.

Conclusion

12. Claims 23-36 and 40-43 are rejected.

13. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

April 21, 2010